

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA	:	CRIMINAL ACTION
	:	
v.	:	
	:	CRIM. NO. 21-132
MURTY VEPURI, et al.	:	(MAG. NO. 21-mj-1220)

**GOVERNMENT'S REPLY IN SUPPORT OF MOTION TO MODIFY THE
COURT'S ORDER RELATED TO FILTER TEAM COMPOSITION**

Because KVK has no legitimate basis to oppose the government's reasonable request for permission to add United States Food & Drug Administration ("FDA") attorneys to the Filter Team, KVK contends that the request is an "astonishing admission" that the government has no evidence that KVK used its alleged "privileged relationship" to engage in fraud. Resp. (ECF 161) at 1-2. The government's motion is neither astonishing nor an admission, and KVK should not succeed in opposing the government's reasonable request with such disingenuous invective. KVK's opposition ignores that the need to add additional resources stems in part from KVK's making overbroad privilege claims involving over 87,000 documents. The request to add attorneys is reasonable and the addition will cause no prejudice to KVK. This Court should grant the government's request to add attorneys from the FDA's Office of Chief Counsel ("OCC") to the Filter Team, on the same terms and subject to the same limitations as the Department of Justice ("DOJ") attorneys who are serving in that role.

First, KVK misleads this Court with a claim unsupported by any reasonable reading of the motion: in KVK's view, the government somehow admits that it cannot identify a reasonable basis "to conclude the Defendants misused a privileged relationship" and, simultaneously, that it "lacks the expertise to identify any violation." Resp. (ECF 161) at

1-2. Neither assertion is correct. Instead, as we stated in our motion, we make this request because OCC attorneys will help “efficiently, thoroughly, and accurately evaluate the merits of KVK’s claims,” without causing “unfair prejudice to KVK.” Mot. (ECF 159) at 1. These additional attorneys would be helpful to the government in the filter review process because KVK’s vast privilege claims involve issues relating to regulatory matters to which FDA attorneys can apply their expertise. The government’s interest in ensuring an accurate and thorough analysis of the many issues presented by KVK is paramount; it is not a concession that the government has abandoned any of its challenges to KVK’s privilege claims.¹

KVK has employed a veritable army of contract attorneys to assess its documents for privilege—and has made many incorrect claims in doing so—yet it seeks to deny the government reasonable resources to evaluate those claims. Moreover, because the OCC attorneys will join the Filter Team, not the prosecution, this addition will only help the parties and the Court. These additional attorneys will only serve to ensure more accurate and complete evaluation of the claims KVK is making, avoiding errors in either direction due to lack of time. They will also help better explicate the issues before the Court, leading to a more just result.

Second, KVK misinforms this Court with its claim that DOJ “restricts FDA-OCC

¹ In the ongoing litigation before the Special Master, the government has argued that as to most of the documents which KVK claims are privileged, KVK cannot sustain its burden of proving either attorney-client or work-product privilege. The government has also argued that the crime fraud exception applies, in part due to evidence that KVK intentionally impeded consultants’ work, failed to follow the law, and then made misrepresentations to the FDA about its remediation efforts. While we do not believe it appropriate to fully address this issue here, requesting the addition of OCC lawyers to address all these issues does not begin to suggest that the government no longer believes that the crime-fraud exception applies.

participation” in enforcement matters. Resp. (ECF 161) at 2. To the contrary, both sources cited by KVK as restricting OCC involvement in litigation contradict KVK’s claim:

[OCC] litigators act as the liaison to the Department of Justice during active litigation, and in many criminal prosecutions have been asked to work as Special Assistant United States Attorneys, assuming primary responsibility for prosecuting violations of the [Food, Drug, and Cosmetic Act] or related statutes. **The litigators frequently work closely with senior officials at the Department of Justice and play an active role in all of FDA’s cases, including matters before the United States District Courts, the Courts of Appeal, and the United States Supreme Court.**

FDA, *Office of the Chief Counsel*, <https://www.fda.gov/about-fda/office-commissioner/office-chief-counsel> (current as of 11/18/2019) (emphasis added); *see also* Justice Manual § 4-8.200 (specifically allowing FDA attorneys to be appointed as Special Assistant U.S. Attorneys, in which capacity they can lead cases on behalf of the United States). It is entirely proper to have OCC counsel involved with DOJ in litigation. For example, already in this case, a thorough analysis of KVK’s privilege claims has required repeated access to systems only available to FDA employees. An OCC attorney who is fully informed of the issues surrounding KVK’s privilege claims would make this process much more efficient—particularly given the volume of KVK’s many privilege claims.

Third, KVK’s claim that DOJ attorneys “lack[] the expertise to identify any violation” simply because there are other attorneys in the government with detailed knowledge of FDA law misstates the nature of what is going on in this matter. Resp. (ECF 161) at 2. KVK has already listed more than 87,000 items on its privilege logs. Mot. (ECF 159) at 2. The breadth and scope of these claims exceeds that which the government reasonably anticipated, and of itself justifies the addition of subject matter experts to the Filter Team. Distinguishing between what is a proper assertion of privilege and what is an improper attempt to evade regulatory requirements, within the enormous body of materials

that KVK asserts are privileged, is a task that is only helped with expertise in FDCA matters that OCC attorneys indisputably have.

Fourth, KVK misleads this Court about the nature of disputes before the Special Master, claiming in a footnote that it “quickly rebutted, with documentation easily accessible to the Filter Team, the two crime-fraud theories the Filter Team has already presented to the Special Master.” Resp. (ECF 161) at 3 n.4. This is false. As KVK well knows, the crime-fraud claims are live issues pending further briefing before the Special Master, with the Filter Team already having begun to demonstrate the invalidity of KVK’s positions.

Fifth, KVK deceptively claims there is no precedent for non-DOJ members to comprise part of a filter team. To the contrary, even a cursory search reveals other agency employees—including non-attorneys—have been involved in a filter team review. *See e.g.*, *Janfeshan v. U.S. Cust. & Border Protec.*, No. 16CV6915ARRLB, 2017 WL 3972461, at *2 (E.D.N.Y. Aug. 21, 2017) (unpublished) (explaining a Customs and Border Patrol filter team was created to address any attorney-client privilege issues that might arise during a search). And it is well-recognized that different subcomponents within DOJ may serve on filter teams. *See In re Search Warrants*, 1:21-CV-04968-SDG, 2021 WL 5917983, at *5 (N.D. Ga. Dec. 15, 2021) (allowing “FBI or other investigating agency personnel assigned to a filter team”); *U.S. v. Elbaz*, 396 F. Supp. 3d 583, 587–88 (D. Md. 2019) (“the Government established a team of attorneys and personnel from the [DOJ] and special agents and other personnel of the [FBI].”). That is similar to what the government is proposing here, which is including attorneys from another federal agency on the Filter Team. KVK further ignores that DOJ routinely uses federal contractors on Filter Teams —

as the Court explicitly allowed for in its order. Order (ECF 87) at 1.

In further effort to support its argument that adding an FDA lawyer to the Filter Team is improper, KVK overstates the holding of Third Circuit caselaw. KVK claims that that the Third Circuit requires that “an independent DOJ attorney acceptable to the district court” to conduct filter review. *See* Resp. (ECF 161) at 4, citing *In re Search of Elec. Commun. in the Account of chakafattah@gmail.com*, 802 F.3d 516, 530 (3d Cir. 2015). In that case, the Court held that the *first level* of a privilege review could not be conducted by non-attorney agents. It did not hold, as KVK contends, that the review must be conducted by DOJ attorneys only, nor did it address the present situation, where the defendant is making broad privilege claims that implicate matters relating to areas of regulatory compliance in which subject matter experts can aid the government in its review. 802 F.3d 516, 530 (3d Cir. 2015). The government is proposing, consistent with *In re Search* and this Court’s order, that the first level of privilege review be conducted by government attorneys and that all members will be supervised by DOJ attorneys.

Finally, KVK’s argument that OCC attorneys will not ethically perform their duties on a filter team because OCC generally “participates in ongoing oversight of regulated products and firms,” is incorrect and contrary to the protections already in place. Resp. (ECF 161) at 4. In this circuit, courts “generally presume that government officials act in good faith” *Cnty. of Butler v. Governor of Pa.*, 8 F.4th 226, 230 (3d Cir. 2021), *cert. denied sub nom. Butler Cnty., Pennsylvania v. Wolf*, 142 S. Ct. 772 (2022). KVK has no support for a presumption that OCC attorneys will violate their ethical duties. To be clear, the attorneys involved in a filter review will not be performing “a shadow FDA inspection.” Resp. (ECF 161) at 3. They will assist with the review of thousands of materials to

determine whether KVK's privilege claims actually have merit and will have the same ethical and legal obligations as anyone else on the team—including being walled off from investigations related to KVK.

In sum, KVK ignores the significance of this Court's procedures that prohibit the Filter Team from sharing privileged information with the Prosecution Team, ignores the government's ethical obligations that the government well understands, and ignores the government's repeated assertions that all lawyers assigned to the Filter Team will serve only in that capacity and will not use any information gleaned in this process against KVK in any way. The current procedures in place state that Filter Team members are not a part of the prosecution team handling the enforcement action, that all Filter Team members will ensure that prosecutors do not gain access to documents protected by the attorney-client privilege, that employees are acting under the supervision of DOJ attorneys, and that the review is conducted solely by attorneys. Order (ECF 87) at 1; *see also* Justice Manual 9-13.420 (E).² In addition, the government has no objection to any OCC attorney being barred from working on any future enforcement matters involving KVK.

Further, this Court has already considered and rejected any arguments that team independence cannot be achieved:

Our Court of Appeals, as set forth above, recognized in 2015 and long after *Klitzman* that the use of a taint team or filter team is a common tool employed by the Government. *In re Search of Elec. Commc'ns*, 802 F.3d at 530. It has also made clear that the district court has discretion in deciding what procedure for review of documents for privilege is to be followed in a particular case. *Id.* In this court's view, the use of a filter team with proper safeguards and limitations in this case will accommodate the need of the Government and indeed the public for an expeditious pretrial proceeding and ultimately for as speedy a trial as possible.

² Available at <https://www.justice.gov/jm/jm-9-13000-obtaining-evidence#9-13.420>.

U.S. v. Vepuri, 21-MJ-1220, 2021 WL 4860744, at *3 (E.D. Pa. Oct. 19, 2021). Any OCC attorneys who join the Filter Team would likewise follow these ethical and legal requirements.

For the foregoing reasons, the government respectfully requests that this Court grant its Motion to allow attorneys from the Food and Drug Administration's Office of Chief Counsel to serve as members of the Filter Team.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I have served a true and correct copy this motion by electronic filing, which provides notice to all attorneys of record in this matter.

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